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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
07/565,673	08/10/90	VAN DER LAAN	J 34363/GBRD-0

EXAMINER
HENDRICKS,K

18M2/0904

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1814	41

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This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 4-22-96

☐ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this ection is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 4-7, 9-15, 19 & 23-37 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Cleim(s) _____ is/are allowed.

☒ Claim(s) 4-7, 9-15, 19 & 23-27 is/ere rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the ettached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oeth or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Applicetion No. (Series Code/Serial Number) _____.

☐ received in this national stage applicetion from the International Bureau (PCT Rule 17.2(e)).

*Certified copies not received: _____.

☐ Acknowledgement is made of e claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Peper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Applicetion, PTO-152

– SEE OFFICE ACTION ON THE FOLLOWING PAGES –

* U.S. GPO: 1996-410-238/40050

Part III DETAILED ACTION

Claim Rejections - 35 USC § 112

112 1st Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. § 112: The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-7, 9-15, 19, 23-29, 30-37 are rejected under 35 U.S.C. § 112, first paragraph, as the disclosure is enabling only for claims limited to methods of producing an alkalophilic asporogenic Bacillus novo species PB92 of minimal natural extracellular protease level, transformed with a B. novo PB92 alkaline protease which has been mutated as described in the specification. Claims 30-33 are included for the same reasons as the previously rejected claims. See M.P.E.P. §§ 706.03(n) and 706.03(z).

The claims are not properly enabled for the recitation of any "mutant high alkaline protease", and any "alkalophilic Bacillus strain". Applicants have again stated that the strain PB92 has been used merely as an example, and that the specification provides enablement for the use of other types of these strains, and for other "mutant high alkaline proteases". Applicants further state that techniques for such are "routine and require no inventive skill or undue experimentation" (quoted from pg. 7, response of 9-7-93). Finally, applicants have stated that "it is not relevant which asporogenic and/or alkalophilic Bacillus strain is used to practice the method" (pg. 8 of the 4-17-96 response).

This is not deemed persuasive for the reasons of record. Applicants have not specifically addressed and traversed any apparent deficiencies in the rejection at hand, and within the reasons of record, and thus the rejection

is maintained. Again and importantly, there is no teaching or reasonable expectation provided that one skilled in the art would be able to utilize the teachings provided for any other systems/genes, or even that there is a problem with any other source such that the instant invention would be applicable. Absent this knowledge, one skilled in the art is left with an undue amount of experimentation, due to the breadth of the claims, in order to attempt to determine what other Bacilli or proteases would be useful in the instant invention, and then further attempt to find the gene and apply the principles taught herein. The specification has not provided pertinent information regarding any other "high alkaline protease" gene, nor any appropriate Bacillus strain that would satisfy the requirements of the invention. This fact is important, as the claims are not commensurate in scope with the specification and its enablement. This information is essential to the function of the claimed invention, and the essential material may not be improperly incorporated into the specification, and does not find support within the teachings of the specification. Thus, one skilled in the art would in no way be enabled to practice the claimed invention with any such gene or strain other than the enabled Bacillus PB92.

Applicants have attempted to add support to the argument by incorporating the statement at page 12 of the specification regarding B. lentus. The Examiner does not see how this statement within the specification provides one skilled in the art with enablement to make and/or use the invention with such a strain. This passage does not appear to connect and directly dictate the use of this strain in the instant method, nor does it provide a reasonable expectation of success, predictability or guidance to use this strain. Even if this were true, the amount of experimentation for one skilled in the art to test this strain, given the parameters discussed in the paragraph above, would be undue, and would not provide enablement for the breadth of the instant claims.

Again, the specification is not properly enabled for claims to any "derivative thereof" of a Bacillus novo species PB92. Applicants state that passages on page 12 of the specification refer to known "derivatives", and that this would be enabling for the instant invention. The phrase "derivatives thereof", however, encompasses predetermined and random mutants of the strain, and progeny of the strain that may or may not contain the gene for the "mutant high alkaline protease" and/or a revertant strain with the indigenous gene. The specification does not properly teach nor describe to one skilled in the art these "derivatives", what specifically they entail, nor how to obtain and/or use such. Mere reference to other teachings, when this is a matter of essential material, without an instant and specific teaching as to how these would be applicable, is not sufficient. Thus, this results in undue experimentation for one skilled in the art to attempt to produce such without proper guidance from the specification. Applicants have amended claims 4 and 13 to avoid this language, however, it remains for claim 31.

While claim 29 was rejected as not properly enabled by the teachings of the specification for the host strain to be "substantially incapable of reversion", new claim 30 was not. This was an oversight on the part of the Examiner. Applicants, however, are encouraged to use these rejections as guidance for the language and enablement of all the claims, and not to assume that the Examiner has performed an exhaustive list of all occurrences (although all such attempts will be made). Applicants appear to have attempted this per the 112 2nd paragraph rejection, in stating that the claims have been amended to delete the word "substantially", however, this occurrence in claim 30 has been overlooked. Claim 30 is rejected for the same reasons of record.

It should again be noted that applicants have pointed out, at page 11 of the response filed 4-17-96, that the Examiner has erred in rejecting claim number 9 under 35 USC 112, 1st paragraph. This is not deemed persuasive. Again, although the claim is specific with regard to the source of the protease gene, it has not overcome all the deficiencies specified above for the claim(s) from which it is dependent (ultimately claim 23). Thus, it is specific and enabled for one aspect (the gene), but not all, including the strain, and is still properly rejected. This is consistent with the rejections maintained above for both the strain and gene.

Claims 26 and 28 are rejected and not enabled for the use of the term "reduced endogenous extracellular protease levels", for the reasons of the rejection set forth with regard to this language in claim 12, etc., as stated at page 3 of the Office Action of 7-15-92 (paper #11). This rejection is in response to applicants amendment, which is an attempt to avoid the new matter rejection of the term "minimal". The phrase "reduced ... levels" has previously been rejected, and applicants have amended other claims to overcome this by the recitation of "no endogenous ... levels".

112 2nd Paragraph

Claims 13, and thus dependent claims 14-15, and claims 26-27, 34, and 35-37 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is rejected as being indefinite as it depends from claim 12. Claim 13 is amended to recite that the strain "contains a mutant high alkaline protease", while the independent claim 12 is not drawn to a method of producing this protease, and does not contain any information as to how this mutant protease is to exist within the strain.

Claim 35 is indefinite for the recitation of lines 2-3, in the deletion of the "protease", as opposed to the intended protease gene.

Claims 35 and 37 are confusing and apparently redundant, as they recite the prevention of reversion within the strains of claims 34 and 36, but these claims already state that the strains are "non-reverting".

Claim 36 is indefinite for the recitation of the term "endogenous" in the second line, while reciting "exogenous" in the last line. It is unclear as to which one is correct and intended, but as currently recited, conflict.

Claim 26 is indefinite and conflicting, as the preamble states that the protease produced is "free of endogenous extracellular protease", but the next line states that the strain only has "reduced levels" of such proteases.

Claim 27 appears to be a substantial duplicate of claim 12. Claim 27 differs from claim 12 only in that in line 5, it does not state "and encoding a replication function". Yet claim 27 requires a replication function in the latter part of the claim, to be inactivated. Thus, the claims do not appear to differ. Also, claim 27 is indefinite as the claim refers to "the replication function" and "said replication function", but these terms lack an antecedent basis within the claim.

Claim 34 is indefinite and incorrect for the recitation of "a non-reverting extracellular protease-negative phenotype", as this is only true of the high-alkaline protease phenotype. Elimination of this gene may/would not necessarily result in a strain being completely free of all extracellular proteases. Further, it is confusing as to the necessity or intent of the phrase "an increased efficiency in production of said mutant high alkaline

protease as compared to an untransformed strain of the same species". If the untransformed strain never (a) produced the mutant protease, or (b) never produced a high alkaline protease, then it follows that it would naturally have an "increased efficiency in production" of the previously non-existing gene.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 19 and 24-25 remain rejected under 35 U.S.C. § 103 as being unpatentable over Fahnestock et al. and Estell et al., in view of TeNijenhuis and Suggs et al. The references and rejection are herein incorporated as cited in a previous Office Action.

The detergent composition and method of preparing such and method for processing laundry utilize "a mutant form of high alkaline protease prepared according to the method of Claim 23". While the remaining claims, directed to methods and strains for producing such proteases are free of the prior art, they do not appear to impart a patentable difference to the protease itself, and thus any detergent composition or method of using or making, each

employing the protease determined to have been obvious from the prior art teachings, would also have been obvious. Again, TeNijenhuis describes the natural protease, and various naturally-occurring mutations would have been expected to occur. Further, the recombinant production and mutation in light of the teachings of the instant references would have made the instant composition and methods obvious, absent any clear and convincing evidence to the contrary. Applicants have recieved patents (5,336,611 and 5,324,653) directed to specific novel and unobvious mutations of the protease, genes, etc. The instant proteases are not directed nor limited to such mutations.

Claims 4-7, 9-15, 23 and 26-34 are free of the prior art. Applicants' arguments have been deemed persuasive.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Keith Hendricks whose telephone number is (703)308-2959.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose phone number is (703)308-0196.

KEITH D. HENDRICKS
PRIMARY EXAMINER
GROUP 1800

kdh
September 3, 1996